



PTO/SB/08a/b (08-03)  
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| Substitution Form 1449A/B/PTO |   |    |   | <b>Complete if Known</b> |                     |
|                               |   |    |   | Application Number       | 10/736,043          |
|                               |   |    |   | Filing Date              | December 15, 2003   |
|                               |   |    |   | First Named Inventor     | Bruce E. Reidenberg |
|                               |   |    |   | Art Unit                 | N/A                 |
|                               |   |    |   | Examiner Name            | Not Yet Assigned    |
| Sheet                         | 1 | of | 1 | Attorney Docket Number   | 02755/100J533-US1   |

| U.S. PATENT DOCUMENTS |                       |  |                                |  |   |
|-----------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                       | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
| 1                     | US-4,806,341          | 02-21-1989                               | Chien et al.                   |  |   |
| 2                     | US-5,026,556          | 06-25-1991                               | Drust et al.                   |  |   |
| 3                     | US-5,069,909          | 12-03-1991                               | Sharma et al.                  |  |   |
| 4                     | US-5,225,199          | 07-06-1993                               | Hidaka et al.                  |  |   |
| 5                     | US-5,240,711          | 08-31-1993                               | Hille et al.                   |  |   |
| 6                     | US-5,613,958          | 03-25-1997                               | Kochinke et al.                |  |   |
| 7                     | US-5,968,547          | 10-19-1999                               | Reder et al.                   |  |   |

| FOREIGN PATENT DOCUMENTS |                       |   |                                |  |   |
|--------------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear |
|                          |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                |  |   |
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| NON PATENT LITERATURE DOCUMENTS |  |   |  |  |                |
|---------------------------------|--|---|--|--|----------------|
| Examiner Initials               | Cite No. <sup>1</sup>  | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  |  |                |
| 8                               | Adrianensen et al., Acta Anaesthesiol Belg 1985;36:33-40   |   |  |  | T <sup>2</sup> |
| 9                               | Brema et al., Int J Clin Pharmacol Res 1996;16:109-116   |   |  |  |                |
| 10                              | Capogna et al., Anaesthesia 1988, 43:128-130   |   |  |  |                |
| 11                              | Goodman & Gilman's The Pharmacological Basis of Therapeutics," J.G. Hardman (Ed.), McGraw-Hill Professional Publishing 2001, pp. 530-532 |   |  |  |                |
| 12                              | Hale et al., Abstract, 08 GSA 2001   |   |  |  |                |
| 13                              | Hale et al., Abstract, Nat'l Clin. Symposium of the American College of Nurse Practitioners; Oct. 2001                                   |   |  |  |                |
| 14                              | Hale et al., J. Clin. Pharmacol. 2001; 41(9):1027, Abstract 58   |   |  |  |                |
| 15                              | Heel et al., Drugs 1979;17:81-110  |   |  |  |                |
| 16                              | Inagaki et al., Anesth Analg 1996;83:530-536   |   |  |  |                |
| 17                              | Nasar et al., Curr Med Res Opin 1986;10:251-255  |   |  |  |                |
| 18                              | Oda et al., Br. J. Anaesthesia 1999;82(6):900-903  |   |  |  |                |
| 19                              | Reidenberg et al., J. Clin. Pharmacol. 2001;41(9):1027, Abstract 57  |   |  |  |                |
| 20                              | Spyker et al., J. Amer. Geriatrics Soc. 2002;50(4):S66, Abstract P162  |   |  |  |                |
| 21                              | Spyker et al., J. Pain 2002;3(2, Suppl. 1):12, Abstract 645  |   |  |  |                |
| 22                              | Spyker et al., J. Pain 2002;3(2,Suppl 1):14, Abstract 653  |   |  |  |                |
| 23                              | Spyker et al., Clin. Pharmacol. Ther. 2000;67(2):145, Abstract PII-12  |   |  |  |                |
| 24                              | Spyker et al., Clin. Pharmacol. Ther. 2001;69(2):P33, Abstract PII-3   |   |  |  |                |
| 25                              | Spyker et al., Conference Abstract presented on October 15, 2001   |   |  |  |                |
| 26                              | Tauzin-Fin et al., Eur J Anaesthesiol 1998;15:147-152  |   |  |  |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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